CLAIMS

1. A process for producing micron-size crystalline particles of a drug substance which comprises mixing a solution of a drug substance to a non-solvent in a container in the presence of ultrasonic energy.
2. A process according to claim 1 in which the drug is a hydrophilic drug.
3. A process according to claim 1 or 2 in which the solvent for hydrophilic drugs is a small chain alcohol.
4. A process according to any one of claims 1 to 3 in which the solvent for hydrophilic drugs is methanol.
5. A process according to claims 1 to 4 in which the anti solvent for hydrophilic drugs is acetionoitrile, 1,1,2,2 tetrafluoroethyl 2,2,2 trifluoroethylether, diethyl ether, acetone, ethyl acetate.
6. A process according to claims 1 to 4 in which the anti solvent for hydrophilic drugs is diethyl ether or acetonitrile.
7. A process according to claim 1 in which the drug is a hydrophobic drug.
8. A process according to claims 1 or 7 in which the solvent for hydrophobic drugs is a small chain alocohol or choloroform.
9. A process according to claim 8 in which the solvent for hydrophobic drugs is methanol or choloroform.
10. A process according to claims 7 to 9 in which the anti solvent for hydrophobic drugs is acetonitrile or water.
11. A process according to claims 7 to 9 in which the anti solvent for hydrophobic drugs is water.
12. A process according to claim 1 in which the drug substance is selected from mometasone, ipratropium bromide, tiotropium and salts thereof, salmeterol, fluticasone propionate, beclomethasone dipropionate, reproterol, clenbuterol, rofleponide and salts, nedocromil, sodium cromoglycate, flunisolide, budesonide, formoterol fumarate dihydrate, Symbicort® (budesonide and formoterol fumarate dihydrate), terbutaline, terbutaline sulphate and base, salbutamol base and sulphate, fenoterol, 3-[2-(4-Hydroxy-2-oxo- 3H-1,3-benzothiazol-7yl) ethylamino]-N-[2-[2-(4- methylphenyl) ethoxy]ethyl] propane sulphonamide, hydrochloride.
13. A process according to any one of claims 1 to 11 in which the solution also conatins water.
14. A process according to any one of claims 1 to 13 in which the ultrasonic energy has a frequency of 20 kHz or more.

15. A process according to any one of claims 1 to 14 in which the ultrasonic energy has an amplitude of between 12 – 260 μm.

16. A process according to any one of claims 1 to 15 in which the burst rate of the ultrasonic energy is from 10% to 100% per second.

17. A process according to any one of claims 1 to 16 in which the reaction temperature is between 5 and 25°C.

18. A drug substance prepared according to a process as defined in any one of claims 1 to 17.

19. A drug substance according to claim 18 which is mometasone, ipratropium bromide, tiotropium and salts thereof, salmeterol, fluticasone propionate, beclomethasone dipropionate, reproterol, clenbuterol, rofleponide and salts, nedocromil, sodium cromoglycate, flunisolide, budesonide, formoterol fumarate dihydrate, Symbicort® (budesonide and formoterol fumarate dihydrate), terbutaline, terbutaline sulphate and base, salbutamol base and sulphate, fenoterol, 3-[2-(4-Hydroxy-2-oxo- 3H-1,3-benzothiazol-7yl) ethylamino]-N-[2-[2-(4- methylphenyl) ethoxy]ethyl] propane sulphonamide, hydrochloride.

20. A drug substance according to any one of claims 18 or 19 having a particle size of 1 to 10 μm